

AVANTA

ORTHOPAEDICS

MAR 16 1998

K974911

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: December 30, 1997

Applicant: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Telephone: 619-452-8580
Fax: 619-452-9945
Contact: Louise M. Focht

Device Name:	External Fixator
Device Trade Name:	External Fixator
Device Classification:	Class II
Reviewing Panel:	Orthopaedic
Regulation Number	888.3040
	Smooth or threaded metallic bone fixation fastener.
Product Code:	JWD
Accessories	
Predicate Device:	EBI/Orthofix K831576

Device Description:

The external fixator like the predicate device includes various size frames, bars, pin clamps, pins, accessories and instruments. The pin clamps enable the frame to be coupled to bone by securing the pins for the intended use. The various components within the system are provided to accommodate various anatomies and injuries.

Intended Use:

The intended use of the external fixation device is the same as that expressed in the predicate device 510k.

The intended use of the external fixator is unilateral external fixation, device which is intended for use in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.

Comparison to Predicate Device:

The table below summarizes similarities and differences between the EBI/Orthofix and the Avanta Orthopaedics external fixator.

Feature	EBI/Orthofix	Avanta Orthopaedics
Pins	Implantable	Implantable
Allows for application of compression or distraction	Yes	Yes
Pin Length	80-160 mm	50-90 mm

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Louise M. Focht
Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, California 92121

MAR 16 1998

Re: K974911
External Fixator
Regulatory Class: II
Product Code: JWD
Dated: December 30, 1997
Received: December 31, 1997

Dear Ms. Focht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

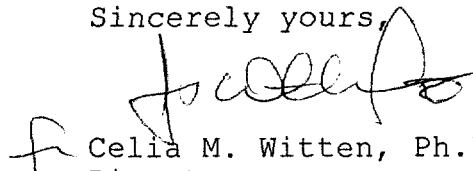
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'C. Witten', is written over the typed name.

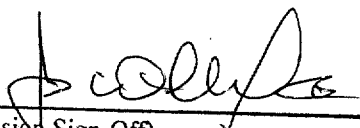
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use:

The intended use of the external fixation device is the same as that expressed in the predicate device 510k.

The intended use of the external fixator is unilateral external fixation, device which is intended for use in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974911

Prescription Use X
(Per 21 CFR 801.109)